

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

45



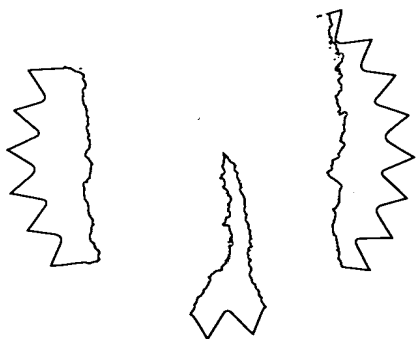
מדינת ישראל
STATE OF ISRAEL

Ministry of Justice
Patent Office

משרד המשפטים
לשכת הפטנטים

This is to certify that annexed
hereto is a true copy of the
documents as originally
deposited with the patent
application of which
particulars are specified on the
first page of the annex.

זאת לתעודה כי רצופים
בזה העתקים נכונים של
המסמכים שהופקדו
לכתחילה עם הבקשה
לפטנט לפי הפרטים
הרשומים בעמוד הראשון
של הנספח.



This 27-02-2002/ היום
רשם הפטנטים
Commissioner of Patents

נתאשר
Certified

ב ק ש ה ל פ ט נ ט Application for Patent

141137	מספר: Number
28-01-2001	תאריך: Date
חוקר/נדרה Ante/Post-dated	

אני, (שם המבקש, מענו ולגבי גוף מאוגד - מקום התאגדותו)
(Name and address of applicant, and in case of body corporate-place of incorporation)

Caesarea Medical Electronics Ltd.
P.O.Box 4294
CAESAREA 38900

קיסריה אלקטרוניקה רפואית בע"מ
ת.ד. 4294
קיסריה 38900

הדין

שם המצאה
of an invention the title of which is

בעל אמצאה מכח
Owner, by virtue of

הממציא: ברק צבי

(בעברית)
(Hebrew)

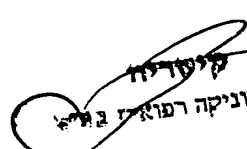
משאבה לנוזלים

(באנגלית)
(English)

Liquid Pump

hereby apply for a patent to be granted to me in respect thereof.

מבקש בזאת כי ינתן לי עליה פטנט

• בקשת חלוקה - Application of Division		• בקשת פטנט מוסיף - Application for Patent Addition		• דרישה רין קדימה Priority Claim		
מבקשת פטנט from Application	לבקשה/לפטנט to Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האגוד Convention Country		
No. dated	No. dated					
• יסודי כללי / מיוחד - רצוף בזה / עוד יוגש P.O.A.: general/individual-attached/to be filed later- הוגש בענין המען למסירת מסמכים בישראל Address for Service in Israel ת.ד. 4294 קיסריה 38900						
חתימת המבקש Signature of Applicant 		שנת of the year				
		בחודש of				
		היום This				
		לשימוש הלשכה For Office Use				



טופס זה, כשהוא מוטבע בחותם לשכת הפטנטים והחותם המודפס, ובהאריך ההגשה, הנו אישור להגשת הבקשה שפרטיה רשומים לציל.
This form, impressed with the Seal of the Patent Office and indicating the number and date of filing, certifies the filing of the application the particulars of which are set out above.

Delete whatever is inapplicable מחק את המיותר

ב ק ש ה ל פ ט נ ט Application for Patent

מספר: Number
תאריך: Date
תוקדם/נדרח Ante/Post-dated

אני, (שם המבקש, מענו ולגבי גוף מאוגד - מקום התאגדותו)
I (Name and address of applicant, and in case of body corporate-place of incorporation)

Caesarea Medical Electronics Ltd.
P.O.Box 4294
CAESAREA 38900

קיסריה אלקטרוניקה רפואית בע"מ
ת.ד. 4294
קיסריה 38900

הדין
בעל אמצאה מכח
Owner, by virtue of
שמה הוא
of an invention the title of which is
הממציא: ברק צבי

משאבה לנוזלים

(בעברית)
(Hebrew)

(באנגלית)
(English)

Liquid Pump

hereby apply for a patent to be granted to me in respect thereof.

מבקש בזאת כי ינתן לי עליה פטנט

• בקשת חלוקה - Application of Division		• בקשת פטנט מוסף - Application for Patent Addition		• דרישה רין קדימה Priority Claim		
מבקשת פטנט from Application	לבקשה/לפטנט to Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האגוד Convention Country		
No. dated	No. dated					
• יפוי כח: כללי / מיוחד - רצוף בזה / צור יוגש P.O.A.: general/individual-attached/to be filed later- הוגש בענין filed in case						
המען למסירת מסמכים בישראל Address for Service in Israel ת.ד. 4294 קיסריה 38900						
חתימת המבקש Signature of Applicant		היום of the year				
		לשם שימוש הלשכה For Office Use				

טופס זה, כשהוא מוטבע בחותם לשכת הפטנטים ומושלם בספר ובתאריך ההגשה, הנו אישור להגשת הבקשה שפרטיה רשומים לעיל.
This form, impressed with the Seal of the Patent Office and indicating the number and date of filing, certifies the filing of the application the particulars of which are set out above.

מחק את הסיוע הבלתי נכון

Liquid Pump

משאבה לנוזלים

APPLICATION FOR PATENT

Inventor: Barak Swi

Title: Liquid Pump

FIELD AND BACKGROUND OF THE INVENTION

This invention relates to pumps and more specifically, it is concerned with a piston pump useful for administration of liquids to a patient through a flexible tube.

Systems for administration of liquids to a patient are widely known. However, a variety of different pumps are available for propelling a liquid to a patient, which may differ, among others, in the manner and principle in which they operate.

The present invention is concerned with two aspects of a system for administering a liquid to a patient. Its first aspect, the invention is concerned with a pumping mechanism for a pump of the aforementioned type. Its second aspect, the invention is concerned with control sensors suitable for use with a high-precision liquid administering pump.

SUMMARY OF THE INVENTION

The invention provides, by a first of its aspects, a piston pump for propelling liquid through a lumen of a flexible tube segment, the pump comprising a first tube clamping member, a first set of tube squeezing members, a second tube clamping member and a second set of tube squeezing members, said members arranged in a direction from upstream to downstream; a synchronizing arrangement for activating the members in a sequential order such that fluid in the tube is displaced in a downstream direction.

The sequential activating order of the elements ensures continuous and repeatable operation of the pump, and comprises the following steps:

- (a) activating the second tube clamping member into blocking the tube's lumen and the first tube clamping member to open the tube's lumen;
- (b) activating the second set of tube squeezing members to constrict the respective tube portion and the first set of tube squeezing members to allow expansion of the respective tube portion;
- (c) activating the first tube clamping member into blocking the tube's lumen;
- (d) activating the second clamping member to open the tube's lumen, and the second set of tube squeezing members to allow expansion of the respective tube portion;
- (e) activating the first set of tube squeezing members to constrict the respective tube portion.

It will be noted, however, that the alphabetic characters used to designate the steps are provided for convenience only and do not imply any particular order of performing the steps.

According to one preferred embodiment of the invention, the first clamping member, the second clamping member and squeezing members of the first and second set are axially displaced along an axis normal to a longitudinal axis of the lumen between an open and a blocked position. Optionally, the pressing surface of the squeezing members can be either flat or designed shaped for designed squeezing.

According to still a preferred embodiment, the sectional area of first set of squeezing members is about twice of that of second set of squeezing members.

By an improved design of the pump there is further provided a counter member associated with a door of the pump, wherein the first and second tube clamping members, clamp the tube against the counter member, and wherein there is further provided a flexible cradle associated at least with the first and second tube squeezing member, for supporting the tube at least at the expanded position, whereby at the expanded position of first and second tube squeezing

members, the tube is pressed between the cradle and the first and second tube squeezing members so as to assume its shape.

The synchronizing arrangement comprises a cam and follower mechanism associated with each of the members and a revolving axle extending parallel to the tube's lumen. According to one possible arrangement there are a number of eccentric members mounted on the axle and being engaged with the tube clamping and the tube squeezing members respectively, for imparting them reciprocal axial displacement in a direction normal to the longitudinal axis, preferably, the eccentric members are normally biased to engage the tube.

By another preferred embodiment, the present invention has a disposal flow set includes a drip chamber, administration tube, valve and a number of squeezing segments; each squeezing segment has a stopper in each end. The stoppers are used for locating the segment in the pumping unit and when a segment loses its flexibility, another segment can be used.

By another preferred embodiment, the present invention includes motor for rotating the axis on which the cams are located.

According to a second aspect of the present invention there is provided a motor and a micro-controller to control the motor revolution in order to achieve an improved linear delivery of the liquid and preventing pulsation effect. The micro-controller controls the motor revolution by using the following algorithm:

- (a) the motor revolution is divided into a number of steps;
- (b) a controller rotates the motor, sequentially from first step to last step of each revolution, wherein each step or a group of steps has an individual speed and an individual pause time between steps or a group of steps;
- (c) the liquid flow, in the output of the pump, is measured in each step and pause; and
- (d) calculating or changing the speed of each step and duration of each pause, to have the desired flow function.

The algorithm can be used sequentially during the pump work, or can be used for one calibration to obtain a revolution function – speed and time for each step and pause - then the controller uses the obtained function to revolve the motor in further work.

According to another aspect of the present invention there is provided a sensor unit for sensing the presence of gas cavities in a liquid flowing through a lumen of a flexible tube segment, the sensor comprising a transmitter unit having an arced transmitter plate with an apex extending along a line defining a

first axis and a receiver unit having an arced receiver plate with an apex extending along a line defining a second axis; the two plates being oppositely arced with their apexes facing one another defining a sensing space between them, the first and the second axes being essentially perpendicular to one another. Typically and preferably the sensor is ultrasonic.

By second preferred embodiment the tube extends through the sensing space such that each of arced transmitter plate and the arced receiver plate contact the tube along it.

By another preferred embodiment, the present invention has communication capability enable it to use any communication infrastructure to deliver information and receive commands.

By another aspect there is provided a dripping sensor for sensing and counting the drips inside the drip chamber.

By another aspect there is provided a sensor unit for a pump adapted for determining the pressure of a liquid flowing within a flexible tube segment, the sensor comprising a tube receiving space formed by walls engaging at least portions of the tube while it is received within the space; and a sensing member projecting into the space for determining deformation-resistance of the tube.

Preferably the sensing member is a plunger associated with a strain gage. The tube receiving space is defined, by a preferred embodiment, between four walls defining a rectangular shape and the plunger projects through one of the walls. By one specific design, the tube receiving space is defined between two or more arced surface.

Preferably, at a non-pressurized state of the tube there remains a known clearance between the walls of the tube receiving space and the tube, whilst the tube is deformed by the plunger also at a non-pressurized state thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

Fig. 1 is an isometric view of a pump in accordance with the present invention comprising a receptacle door being opened prior to engagement with a tube segment;

Fig. 2 is an illustration of a disposal flow set;

Figs. 3a -3d show, in isolation, the piston mechanism, in continuous consecutive phases of the pump's operation;

Fig. 4 is a sectional view of a pressure sensing unit for incorporation in a pump of the aforementioned type;

Fig. 5 is a perspective, exploded view of a gas detection sensor for use in a pump of the aforementioned type; and

Figs. 6A and 6B are side views of the device seen in Fig. 4 rotated by 90°.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Reference is first being made to Fig. 1 in which a piston pump generally designated 10 is shown, comprising a housing 12, having a user interface unit 14 and a pumping assembly, generally designated 16. Typically, user interface 14 comprises a key pad 18, for input of data such as flow rate, flow time, etc. and to initiate or stop the pump and a display 22.

The pumping assembly 16 comprises a door 30 pivotally engaged at pivots to a support structure of the pump (not seen). Door 30 comprises a release lever 35, a biasing spring (not seen) and an engaging hook portion 38 adapted for engagement with a corresponding lateral shoulder of a locking recess formed in the housing 12.

Door 30 carries also a counter member 15, which in the present embodiment is spring-biased by means of springs 52. The counter member 15 may be a rigid bar covered by a layer of flexible material or, it may also be

made of a flexible material, e.g. a bar of silicon rubber, etc. The purpose of this counter member 15 will become apparent hereinafter.

The housing is formed with a receptacle 41 for receiving a segment - between two stoppers 63 - of a flexible tube 62 of a flow set 34 such as of a drug administration set, etc. The receptacle 41 extends across the housing 12 between openings formed in the side walls of the housing 12. Receptacle 41 is also formed with two-well shaped portions and a major receptacle portion. It is further noted that the door 30 comprises a tube positioning extension 55 for depressing and positioning the tube 62 within the receptacle 41 at the openings of the housing. Furthermore, the receptacle may be provided with a micro switch (not shown) for generating a signal to the control unit of the pump, indicative of engagement of the pump with a segment of the tube. Suitable sensor means may also be provided to indicate proper closure of door 30. Two openings 37 are formed one in the door 30 and the other in the housing 12 to locate two parts of an air sensor. A pressure sensor 36 is located in the housing 12 between two sides of the tube 62.

Fig. 2 illustrates a disposal flow set for use with the pump in order to administer a liquid. The flow set 60 includes an administration tube 61, which is separated into a number of pumping segments 62 wherein each segment is bordered by two stoppers 63. The stoppers 63 are used to locate one of the

pumping segment in the pump and when a segment loses its flexibility it can be replaced by another segment. The flow set 60 includes a dripping chamber 64 that can be used, inter alia, for sensing and counting the drops passing through the chamber using a drip sensor (not shown). The flow set 60 includes a valve 65 and a connector 66 to connect the set to a patient.

Figs. 3a - 3d show, in isolation, the piston mechanism, in continuous consecutive phases of the pump's operation. The pump includes a first clamping member 71, a first set of squeezing members 76, a second clamping member 77, a second set of squeezing members 78, an axis 74 with a number of eccentric cams 75 installed on the axis to elevate and to lower each member according to the pumping sequence in order to clamp and squeeze a tube segment 62 to administrate the liquid flow 73 from right to left.

In a first step, (Fig. 3a) the axis 74, with the eccentric cams 75, is revolved to a position that elevates the first clamping member 71 by an associated cam 75a and the first clamping member clamps the right end of the tube segment 62. In a further stage of Fig. 3b, the axis 74 continues its revolution and first set of squeezing members are elevated by associated cams 75b. The squeezing members 76 squeeze the tube segment 62 and force the liquid 73 to move left. In the next step (Fig. 3c), by the continuation of the axis 74 revolve, the second clamping member 77 is elevated by an associated cam

75c and clamps the tube segment 62 in the left end of the squeezed area. In a meanwhile, the second squeezing set 78 is still elevated since the previous sequence, by the associated cams 75d, and start to move down to ensure the continuation flow of the liquid 73.

In the last sequential step (Fig. 3d), by the continuation of the axis 74 revolve, the second set of squeezing members 78 are finished elevating and in the meanwhile the first set of squeezing members 76 and the first clamping member 71 are lowed down by the associated cams 75a & 75b. While the left liquid 73 is pushed to the left, a new liquid 79 from a container (not shown) fills the right released part of the tube segment 62, ready for the next sequence of the pump when the second set of squeezing members 78 and the second clamping member 77 are low down and the first clamping member 71 is elevate up.

For best performances, it is desired that the squeezing size area of the first set of squeezing members 76 is about double the size of the squeezing size area of the second set of squeezing members 78, so as to ensure continuous propelling of liquid in a downward direction, where the volume of liquid received within the tube segment corresponding with the area of tube squeezing members 76 serves as a reservoir of liquid.

The cams are angularly diverted such that at least one or more of the cam followers constitute the first tube clamping member, one or more other cam followers constitute the second tube clamping member, several other cam followers arranged in the same orientation constitute the first set of tube squeezing members, and several other cam followers arranged in the same orientation constitute the second set of tube squeezing members.

Different parameters are maintained similar to the previous embodiment, e.g., the tube blocking cam followers engage the respective tube segment so as to essentially block the tube's lumen, whilst the tube squeezing cam followers engage the respective tube segment to only partially squeeze the tube's lumen. This may be achieved by differently forming the tube-engaging surface of the cam followers, or by shortening their lengths or by different forms of the cams.

In Fig. 4 of the drawings, there is illustrated a pressure sensing device 170 incorporated into the pump in accordance with the present invention, or other liquid administering pumps, and is suitable for placing within one of the cavities 46 or 48 formed in the housing 12. The sensor unit 170 comprises a U-like receptacle 172 dimensioned so as to comfortably accommodate tube 62, with a suitable counter member 50 closing the structure from above. A plunger 174 projects into the space 176 confined within the U-like receptacle 172 through a suitable opening at a bottom wall thereof 178 and is associated with a

pressure sensing gauge 180, e.g. a piezo-electric gauge, string gauge, etc. for detecting pressure applied thereto by the tube 62, depending on its internal pressure applied by the liquid flowing through its lumen.

The arrangement of the sensor 170 ensures that local deformation of the tube is converted into terms of pressure without influence of overall deformation of the tube caused by the internal pressure of the liquid, this owing to the support walls of structure 172 preventing undesired deformation of the tube.

Figs. 5 and 6 illustrate a sensor for detecting the presence of gas, typically air, flowing within the liquid carrying tube. The device, generally designated 190 is suitable for insertion within one of the cavities 46 or 48 of housing 12 and comprises a transmitter unit 192 having an arced transmitter plate 196 and a receiver unit 194 having an arced receiver plate 198 with the two plates 196 and 198 being oppositely arced with their apexes facing one another defining between them a sensing space 200 (Figs. 6A and 6B). In order to achieve sensing focus, the two plates 196 and 198 are perpendiculars each other. Typically the sensor is ultrasonic.

The arrangement is such that the entire cross-section of the tube is covered by the ultrasonic waves thereby any air cavities, even in significantly

small with respect to the cross-section of the tube, and even if not flowing axially centered within the tube, are detected.

Whilst preferred embodiments have been shown and described, it is to be understood that it is not intended thereby to limit the disclosure of the invention, but rather it is intended to cover all modifications and arrangements falling within the spirit and the scope of the invention, *mutatis mutandis*.

WHAT IS CLAIMED IS:

1. A piston pump for propelling liquid through a lumen of a flexible tube segment comprising a first tube clamping member, a first set of tube squeezing members, a second tube clamping member and a second set of tube squeezing members, said members arranged in a direction from upstream to downstream, a motor and a synchronizing arrangement for activating the members in a sequential order such that fluid in the tube is displaced in a downstream direction.
2. The piston pump of claim 1, further comprising a disposal flow set wherein said flow set includes a drip chamber, a valve, a flexible tube and at least one squeezing segment on said flexible tube wherein each of said squeezing segment bounded by two stoppers – a stopper in each end.
3. A piston pump of claim 2, wherein the sequential activating order is:
 - (a) activating said second tube clamping member into blocking the lumen of a tube of said flow set tube and said first tube clamping member to open the lumen of said tube of said flow set tube;
 - (b) activating said second set of tube squeezing members to constrict a respective tube portion and said first set of tube squeezing members to allow expansion of said respective tube portion;

- (c) activating said first tube clamping member into blocking said tube's lumen;
 - (d) activating said second clamping member to open said tube's lumen, and said second set of tube squeezing members to allow expansion of said respective tube portion;
 - (e) activating said first set of tube squeezing members to constrict said respective tube portion.
-
- 4. The piston pump of claim 3, wherein the pressing surface of said squeezing members is designed for designed squeezing.
 - 5. The piston pump of claim 3, wherein the squeezing area of said first set of squeezing members is about twice of the area of said second set of squeezing members.
 - 6. The piston pump of claim 3, further comprising a synchronizing arrangement includes an axis and a number of eccentric cams, a cam for each said clamping or squeezing member, for moving said members up and down.
 - 7. The piston pump of claim 6, further comprising a motor to revolve said synchronizing arrangement.

8. The piston pump of claim 1, further comprising an ultrasonic gas-cavities sensor for discovering a liquid lack in said tube.
9. The piston pump of claim 1, further comprising a communication capability, enable to use any communication infrastructure for delivering information and receiving commands.
10. The piston pump of claim 2, further comprising a dripping sensor for sensing and counting the drips passing through said dripping chamber.
11. The piston pump of claim 2, further comprising a sensor unit adapted for determining the pressure of a liquid flowing within said flexible tube, wherein the sensor includes a tube receiving space formed by walls engaging at least portions of said tube while said receiving space is received within the space and a sensing member projecting into the space for determining deformation-resistance of said tube.
12. The piston pump of claim 11, wherein said sensing member is a plunger associated with a strain gage and said receiving space is defined a rectangular shape and said plunger projects through one of the walls of said tube.

13. The piston pump of claim 7, wherein said motor revolved by a controller into a nonlinear revolution to achieve linear flow of liquid, by using an algorithm for revolving a motor in a specific nonlinear revolution, comprising:
 - (a) the motor revolution is divided into a number of steps;
 - (b) a controller rotates said motor, sequentially from first step to last step of each revolution, wherein each step or a group of steps has an individual speed and an individual pause time between steps or a group of steps;
 - (c) the liquid flow, in the output of the pump, is measured in each said step and in each said pause;
 - (d) calculating or changing the speed of each said step and duration of each said pause, to have the desired flow function; and
 - (e) storing the function of the nonlinear revolution of said motor, in a memory.
14. The piston pump of claim 13, wherein said algorithm is used sequentially during said pump work.

15. The piston pump of claim 13, wherein said algorithm is used for ones calibration to obtain said function of nonlinear revolution and said controller uses the obtained function to revolve said motor in further work.

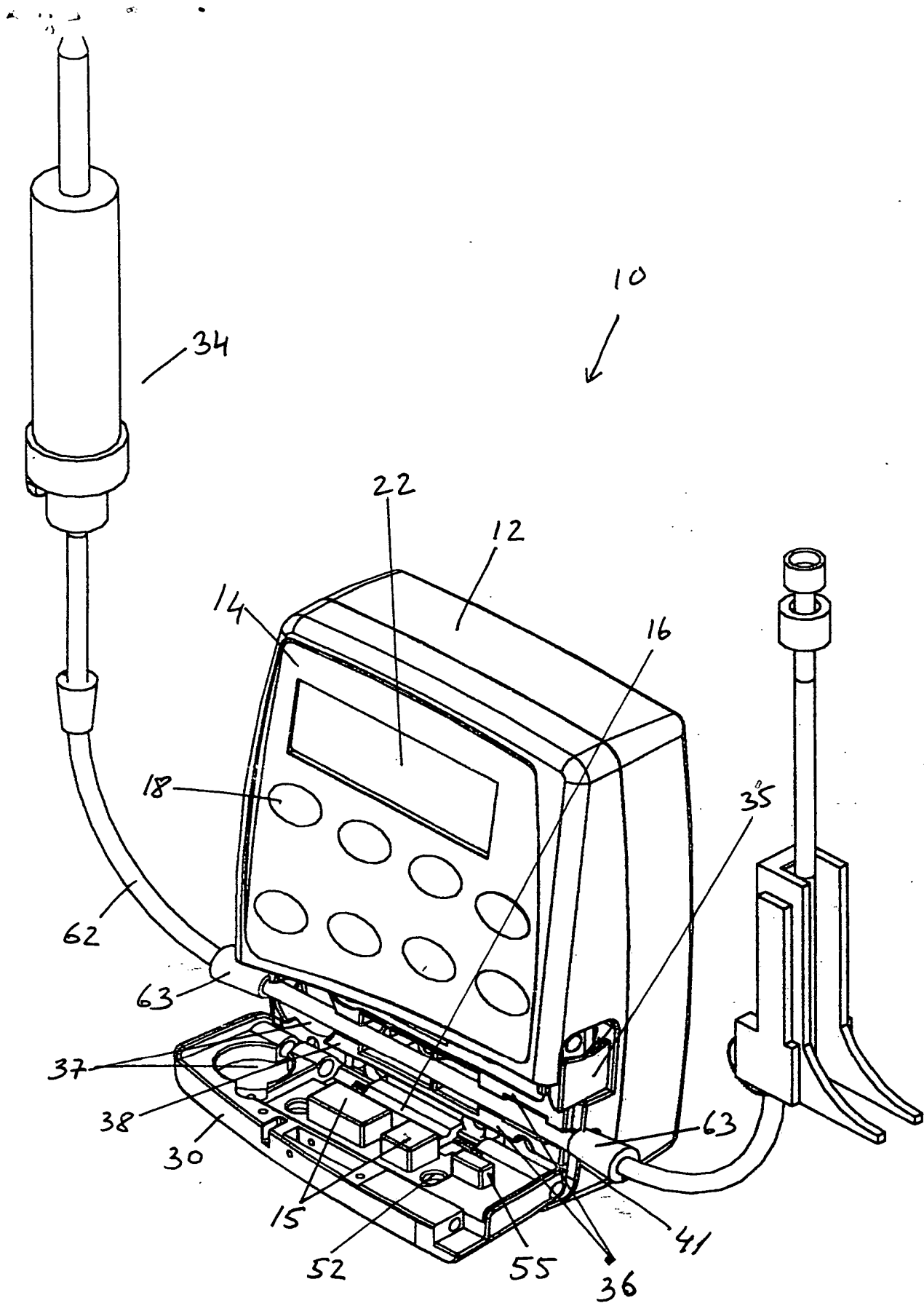


FIGURE 1

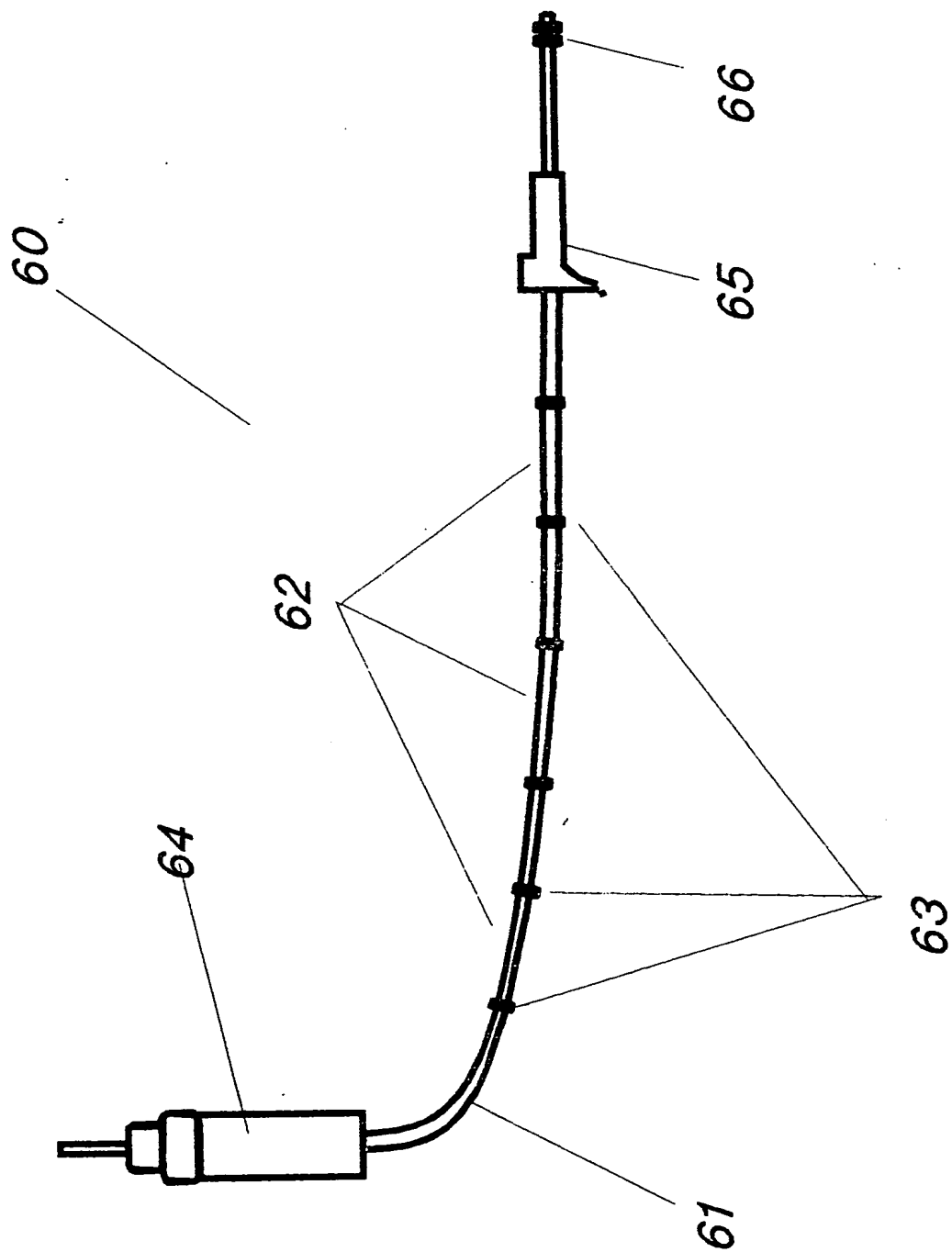
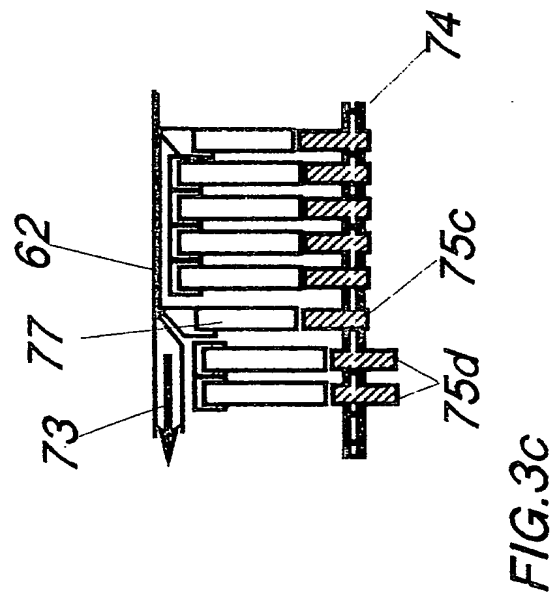
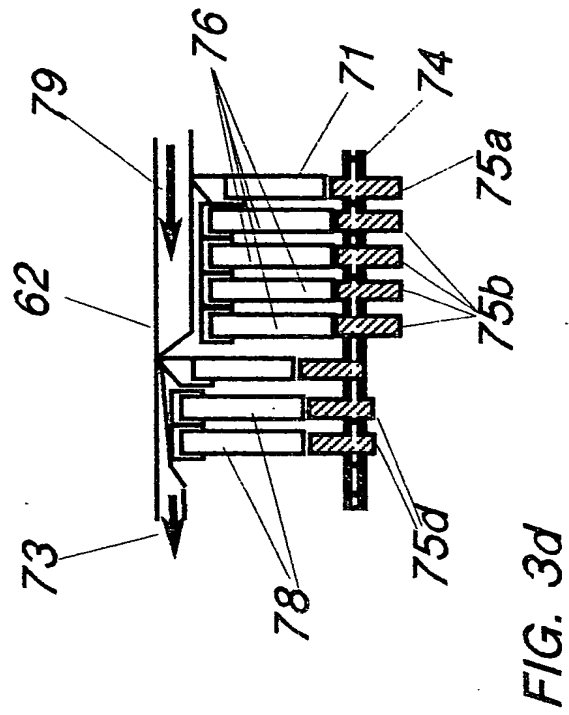
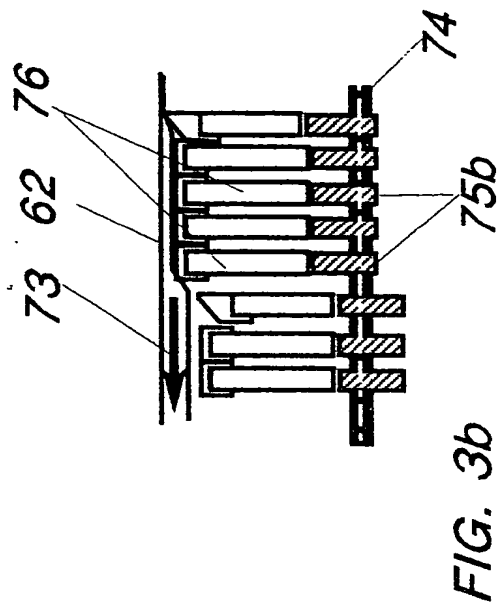
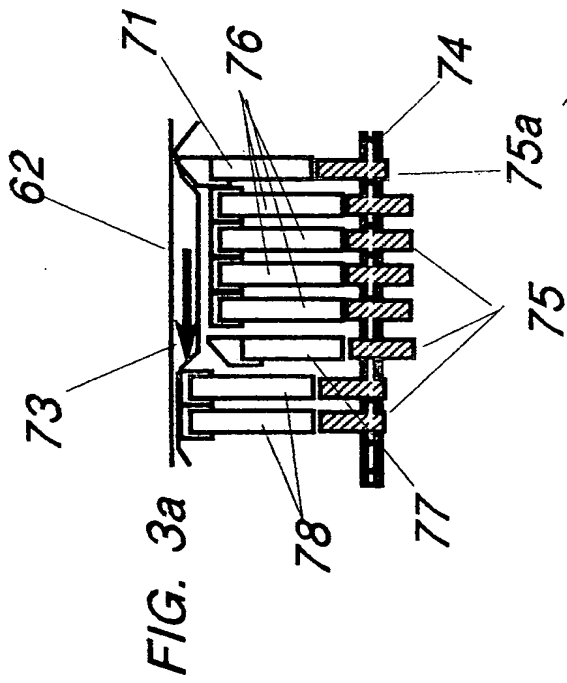


FIG. 2



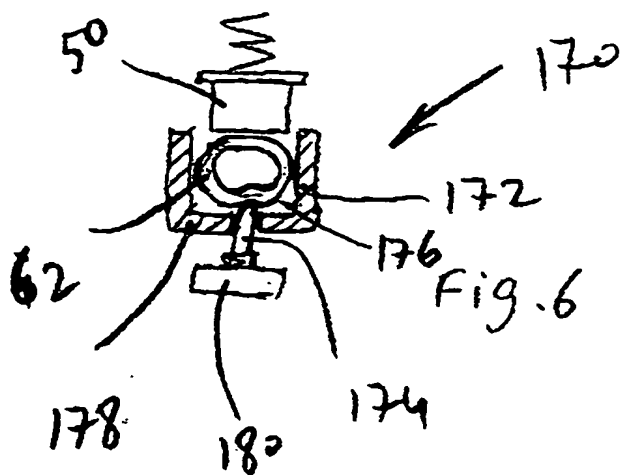


FIG. 6A

